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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. CONFIRMATION NO			
10/784,046	02/20/2004	Claude Mathieu	8932-823-999	6834		
20583 JONES DAY	7590 11/19/200	7	EXAMINER			
222 EAST 41S	- <del>-</del> -	PELLEGRINO, BRIAN E				
NEW YORK, N	NY 10017	•	ART UNIT	PAPER NUMBER		
			3738			
	•	,	MAIL DATE	DELIVERY MODE		
			11/19/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Applicatio	n No.	Applicant(s)			
į t	•	10/784,04	6	MATHIEU ET AL.	C		
Office Action Summary		Examiner		Art Unit			
		Brian E. Pe	ellegrino	3738			
	MAILING DATE of this communication	on appears on the	cover sheet with	the correspondence addres	'S		
Period for Reply							
WHICHEVE  - Extensions of t after SIX (6) M  - If NO period fo  - Failure to reply Any reply recei	IED STATUTORY PERIOD FOR I R IS LONGER, FROM THE MAILI ime may be available under the provisions of 37 ONTHS from the mailing date of this communica r reply is specified above, the maximum statutory within the set or extended period for reply will, b ved by the Office later than three months after the term adjustment. See 37 CFR 1.704(b).	NG DATE OF TH CFR 1.136(a). In no eve tion. y period will apply and will by statute, cause the appli	IS COMMUNICA  nt, however, may a repl  expire SIX (6) MONTH cation to become ABAN	ATION. y be timely filed IS from the mailing date of this commul NDONED (35 U.S.C. § 133).			
Status							
1)⊠ Respo	nsive to communication(s) filed or	n <u>05 September 2</u>	<u>007</u> .				
2a)⊠ This a	∑ This action is FINAL. 2b) This action is non-final.						
•	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed	in accordance with the practice u	nder Ex parte Qu	<i>ayle</i> , 1935 C.D. <i>1</i>	11, 453 O.G. 213.			
Disposition of (	Claims						
-	(s) <u>33-91</u> is/are pending in the app	lication.					
•	the above claim(s) <u>37-42,54-59,62</u>		-91 is/are withdr	awn from consideration.			
-	(s) <u>60,61,64 and 69-80</u> is/are allow						
·	(s) <u>33-36 and 43-53</u> is/are rejected						
,	(s) is/are objected to.						
8) Claim	(s) are subject to restriction	and/or election re	equirement.				
Application Pa	pers						
9)∏ The sp	ecification is objected to by the Ex	caminer.					
	awing(s) filed on is/are: a)[		objected to by	the Examiner.			
• •	ant may not request that any objection						
•	ement drawing sheet(s) including the						
11) <u></u> The oa	th or declaration is objected to by	the Examiner. No	ite the attached (	Office Action or form PTO-1	152.		
Priority under 3	35 U.S.C. § 119						
12) Acknow	wledgment is made of a claim for f	foreign priority und	der 35 U.S.C. § 1	l 19(a)-(d) or (f).			
a)∏ All	b) ☐ Some * c) ☐ None of:						
	Certified copies of the priority doc						
	Certified copies of the priority doc						
	Copies of the certified copies of the			eceived in this National Sta	ge		
	application from the International			· nacivad			
* See the	attached detailed Office action fo	r a list of the certi	ned copies not re	eceivea.			
,							
Attachment(s)							
	erences Cited (PTO-892) ftsperson's Patent Drawing Review (PTO-	948)	Paper No(s)/	mmary (PTO-413) Mail Date			
3) 🔲 Information D	Disclosure Statement(s) (PTO-1449 or PTC		5) Notice of Info	ormal Patent Application (PTO-152	2)		
Paper No(s)/	Mail Date		6)	<u>-•</u>			

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#### **DETAILED ACTION**

# Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33,34,36,44-46,48,49 are rejected under 35 U.S.C. 102(e) as being anticipated by Suddaby (6174334). Fig. 1 shows a spinal prosthesis with first and second halves 10,12 with each having a "process" portion 18 or section that is fully capable of being placed on a side of the spinous process. It can also be seen the prosthesis has coupling portions 14,16 which have recesses and projections that lock together. Fig. 2 shows the halves are axially fixed with respect to each other. Suddaby discloses the coupling portions are sized and configured to be elastically deformable, col. 4, lines 11-13. Regarding claim 44, Suddaby disclose the implant is made of metal, col. 4, lines 23,24. With respect to claim 45, Suddaby illustrates (Fig. 1) the implant surface should have windows 20 for enhancing bone ingrowth, col. 4, lines 2-4. Regarding claim 46, Fig. 2 shows the implant having a roughened surface with projections 30.

Claims 33,34,36,44,48,49,51 are rejected under 35 U.S.C. 102(b) as being anticipated by Zucherman et al. (5836948). Fig. 14 shows a spinal process implant with first 112 and second 114 halves with coupling portions 116,118 respectively that are in the form of a projection and recess with the internal structure having a stop or angled surface to prevent the projection from coming out. Zucherman discloses that upon

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elastically deforming the coupling, the two halves are locked together, col. 5, lines 51-52. Zucherman discloses materials for the implant can be metal, col. 4, lines 17-19. The implant is placed on either side of the spinous process, col. 5, lines 58-60.

## Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. '948 in view of Howland et al. (5496318). Zucherman is explained supra. However, Zucherman et al. fail to disclose the complimentary halves have a key and keyway. Howland et al. teach (Figs. 10-13. the halves of a spinous process implant comprise keyway 122 and a complementary "key" 124 to prevent rotation of the implant halves. It would have been obvious to one of ordinary skill in the art to incorporate the "key" and keyway as taught by Howland et al. with the device of Zucherman et al. such that it keeps the components together in the patient and prevents rotation.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suddaby '334 in view of Campbell (5261908). Suddaby is explained above. Suddaby does disclose plastic can be used for the implant, col. 4, lines 24-26. However, Suddaby fails to disclose a portion of the first and second halves having an elastomeric material. Campbell teaches (Figs. 16a,b) the use of elastomeric material as prosthetic plate members, col. 4, lines 61-65. It would have been obvious to one of ordinary skill in the art to use alternative material for the plates such as an elastomeric material as taught

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by Campbell for the prosthesis of Suddaby for its lightweight property and provide a good pliable material.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suddaby '334 in view of Taylor (WO 95/31158). Suddaby is explained above. However, Suddaby fails to disclose a hydroxyapatite coating on the exterior surface of the process portions. Taylor teaches the use of a hydroxyapatite coating on the surface to promote bone ingrowth, abstract. It would have been obvious to one of ordinary skill in the art to coat the surface with hydroxyapatite as taught by Taylor on the implant of Suddaby such that it enhances osteo-integration.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Zucherman et al. '948 in view of Lang et al. (6524341). Zucherman is explained supra.

However, Zucherman et al. fail to disclose one half of the prosthesis has a radially
projecting tab to correspond with a groove in the second half of the implant to prevent
movement. Lang et al. teach (Fig. 4) a spinal prosthesis with the first half having radially
projecting tabs and the second half comprises grooves to receive the tabs. Lang et al.

also teaches the prosthesis is designed such that the first and second halves are to be
locked to prevent rotation, col. 5, lines 46-49. It would have been obvious to one of
ordinary skill in the art to modify the engagement structure of the implant halves and
have a tab and groove arrangement as taught by Lang et al. for the implant of
Zucherman et al. such that it prevents movement from the implanted position.

Claims 52,53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suddaby '334. Suddaby is explained supra. However, Suddaby fails to disclose the

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dimensions of the coupling portions or the dimensions of the process portions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a cross-sectional dimension 50mm² to 300mm² for the coupling portions or a range between 70mm² to 500mm² for the cross sectional dimension of the process portions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### Response to Arguments

Applicant's arguments with respect to claim 33 have been considered but are most in view of the new ground(s) of rejection.

### Allowable Subject Matter

Claims 60,61,64,69-80 are allowed.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (8:30am-5pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BRIAN E. PELLEGRINO PRIMARY EXAMINED

Brian E Rell